

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC., &
UNIVERSITY OF WASHINGTON,

Plaintiffs,

v.

GUARDANT HEALTH, INC.,

Defendant.

C.A. No. 21-1126-LPS

JURY TRIAL DEMANDED

**DEFENDANT GUARDANT HEALTH, INC.’S ANSWER AND
AFFIRMATIVE DEFENSES TO PLAINTIFFS’ COMPLAINT**

Defendant Guardant Health, Inc. (“Guardant”) hereby answers the Complaint filed by TwinStrand Biosciences, Inc., (“TwinStrand”) and University of Washington (“UW,” collectively, “Plaintiffs”) on August 3, 2021 as follows.

Except as expressly admitted, Guardant denies each and every allegation of Plaintiffs’ Complaint. Guardant’s specific responses to the numbered allegations are set forth below and correspond to the numbered allegations in Plaintiffs’ Complaint. The opening paragraph of Plaintiffs’ Complaint does not appear to contain any allegations requiring a response. To the extent the opening paragraph contains allegations directed to Guardant, Guardant admits that Plaintiffs’ pleading purports to be a complaint for patent infringement, but denies that Guardant has infringed any valid and enforceable patent claim or that Plaintiffs are entitled to any relief.

For ease of reference, Guardant has included the headings from Plaintiffs’ Complaint. The inclusion of these headings is not an admission by Guardant and to the extent that any heading or other non-numbered statement in Plaintiffs’ Complaint contains or implies any allegations, Guardant denies each and every allegation therein.

NATURE OF THE ACTION

1. Guardant admits that the Complaint alleges infringement of United States Patent Nos. 10,287,631 (“the ’631 patent”); 10,689,699 (“the ’699 patent”); 10,752,951 (“the ’951 patent”); and 10,760,127 (“the ’127 patent”) (collectively, “the Asserted Patents”) under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Guardant denies that Plaintiffs are entitled to any relief, including any relief under the patent laws of the United States. Except as expressly admitted herein, Guardant denies each and every allegation contained in Paragraph 1 of the Complaint.

THE PARTIES

2. Guardant is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

3. Guardant is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

4. Guardant admits that Guardant is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 505 Penobscot Dr., Redwood City, CA 94063.

JURISDICTION AND VENUE

5. Guardant admits that Plaintiffs purport to assert claims for patent infringement but denies that Guardant has infringed any valid and enforceable patent claim or that Plaintiffs are entitled to any relief. For purposes of this action, Guardant admits that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 to the extent that Plaintiffs are able to demonstrate a proper claim for patent infringement. The remaining allegations of this paragraph are legal conclusions, and, on that basis, Guardant denies them

6. Guardant admits that it is a Delaware corporation. For purposes of this action, Guardant does not contest personal jurisdiction. The remaining allegations of this paragraph are legal conclusions, and, on that basis, Guardant denies them.

7. For purposes of this action, Guardant does not contest personal jurisdiction, but it denies committing, directly or indirectly, any acts of infringement. The remaining allegations of this paragraph are legal conclusions, and, on that basis, Guardant denies them.

8. Guardant admits that Guardant is a Delaware corporation. For purposes of this action, Guardant does not contest that venue is proper but denies that venue is convenient. The remaining allegations of this paragraph are legal conclusions, and, on that basis, Guardant denies them.

THE PATENTS-IN-SUIT

9. Guardant admits that a document that purports to be a copy of the '631 patent is attached as Exhibit A to the Complaint. On its face, Exhibit A appears to be entitled "Methods of Lowering the Error Rate of Massively Parallel DNA Sequencing Using Duplex Consensus Sequencing" and appears to have been issued on May 14, 2019. Guardant denies the remaining allegations of this paragraph.

10. Guardant admits that a document that purports to be a copy of the '699 patent is attached as Exhibit B to the Complaint. On its face, Exhibit B appears to be entitled "Methods of Lowering the Error Rate of Massively Parallel DNA Sequencing Using Duplex Consensus Sequencing" and appears to have been issued on June 23, 2020. Guardant denies the remaining allegations of this paragraph.

11. Guardant admits that a document that purports to be a copy of the '951 patent is attached as Exhibit C to the Complaint. On its face, Exhibit C appears to be entitled "Methods of

Lowering the Error Rate of Massively Parallel DNA Sequencing Using Duplex Consensus Sequencing” and appears to have been issued on August 25, 2020. Guardant denies the remaining allegations of this paragraph.

12. Guardant admits that a document that purports to be a copy of the ’127 patent is attached as Exhibit D to the Complaint. On its face, Exhibit D appears to be entitled “Methods of Lowering the Error Rate of Massively Parallel DNA Sequencing Using Duplex Consensus Sequencing” and appears to have been issued on September 1, 2020. Guardant denies the remaining allegations of this paragraph.

BACKGROUND

13. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

14. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

A. The Need for High-Accuracy, High-Throughput Sequencing Methods

15. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that detecting genetic mutations is important in the diagnosis of cancers and other illnesses. As to the remaining allegations, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

16. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that a sequencing method known as Sanger sequencing was used in some manner as part of the Human Genome Project. As to the remaining allegations, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

17. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that, in general, some forms of Next Generation Sequencing (“NGS”) have the ability to sequence DNA molecules at a much higher throughput compared to older sequencing methods. As to the remaining allegations, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

18. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

B. The Inventions

19. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

20. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however,

Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

21. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

22. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

23. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

24. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

25. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

26. The allegations made in this paragraph do not appear to be directed at Guardant, and therefore no response is required. To the extent any response may be required, however, Guardant states that it lacks knowledge or information sufficient to form a belief about the truth of the allegations and thus denies the same.

C. Guardant's [Alleged] Willful Infringement of the Asserted Patents

1. Guardant's [Alleged] infringing products and services

27. Guardant admits that it began selling certain products and services under the moniker "Digital Sequencing Technology" within the United States in 2014. Guardant admits that a document that purports to be a copy of the Guardant IPO Prospectus is attached as Exhibit F to the Complaint. Except as expressly admitted, Guardant denies the allegations of this paragraph.

28. Guardant admits that it sells diagnostic kits with the names Guardant360 lab developed test ("LDT"), Guardant360 CDx ("CDx"), GuardantOMNI ("Omni"), Guardant Reveal1 ("Reveal"), Guardant LUNAR-2 ("LUNAR-2"), Guardant360 Response, and Guardant360 TissueNext (collectively, the "Guardant Kits"). Guardant admits that it has customers outside of the United States. Except as expressly admitted, Guardant denies the allegations of this paragraph.

29. Guardant admits that in 2017, Dr. Rick Lanman was Guardant's Chief Medical Officer. As to the remaining allegations of this paragraph, Guardant is without knowledge or information sufficient at this time to form a belief as to the truth of the allegations of this paragraph and, on that basis, denies them.

30. Guardant admits that it provides certain data services to its customers and that it uses the terms Guardant Connect and Guardant Inform (collectively, "the Guardant Services") to

describe some of its services. Except as expressly admitted, Guardant denies the allegations of this paragraph.

2. Guardant [allegedly] knew or should have known of the Asserted Patents and that its conduct amounted to infringement

31. Guardant admits that it attempted to license certain technology from UW. Except as expressly admitted, Guardant denies the allegations of this paragraph.

32. Guardant admits that during prosecution of its patents, it has cited certain patents and publications to the United States Patent & Trademark Office (“PTO”), including certain Asserted Patents and published patent applications belonging to Plaintiffs. Guardant further admits that during prosecution of its patents, the PTO has referenced certain Asserted Patents belonging to Plaintiffs. Except as expressly admitted, Guardant denies the allegations of this paragraph.

33. Guardant admits that the Petition for *Inter Partes* Review in *Foundation Medicine, Inc. v. Guardant Health, Inc.*, PTAB IPR2019-00130, alleged that U.S. Patent No. 9,752,188 is purportedly prior art to Guardant’s U.S. Patent 9,598,731. Guardant also admits that the Petition for *Inter Partes* Review in *Foundation Medicine, Inc. v. Guardant Health, Inc.*, PTAB IPR2019-00653, alleged that U.S. Patent No. 9,752,188 is purportedly prior art to Guardant’s U.S. Patent 9,843,822. Guardant further admits that the Petition in PTAB IPR2019-00653 includes U.S. Provisional Application 61/613,413 as EX1012. Except as expressly admitted, Guardant denies the allegations of this paragraph.

34. Guardant admits that PCT application 2013/032665 was cited in EPO proceedings regarding Guardant’s European Patent Nos. 3087204, 3378952, and 2893040. Except as expressly admitted, Guardant denies the allegations of this paragraph.

35. Guardant denies the allegations of this paragraph.

COUNT I

([Alleged] Direct Infringement of U.S. Patent No. 10,287,631)

36. Guardant incorporates its responses to Paragraphs 1-35 above, as if fully set forth herein.

37. Guardant admits that this paragraph recites claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

38. Guardant denies the allegations of this paragraph.

39. Guardant admits that this paragraph recites a portion of the preamble from claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

40. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

41. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

42. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

43. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

44. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

45. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

46. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

47. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

48. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

49. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

50. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

51. Guardant admits that this paragraph recites a portion of claim 1 of the '631 Patent as set forth in Exhibit A. Except as expressly admitted, Guardant denies the allegations of this paragraph.

52. Guardant denies the allegations of this paragraph.

53. Guardant denies the allegations of this paragraph.

54. Guardant denies the allegations of this paragraph.

55. Guardant denies the allegations of this paragraph.

56. Guardant denies the allegations of this paragraph.

COUNT II

([Alleged] Infringement of U.S. Patent No. 10,689,699)

57. Guardant incorporates its responses to Paragraphs 1-56 above, as if fully set forth herein.

58. Guardant admits that this paragraph recites claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

59. Guardant denies the allegations of this paragraph.

60. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

61. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

62. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

63. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

64. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

65. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

66. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

67. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

68. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

69. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

70. Guardant admits that this paragraph recites a portion of claim 1 of the '699 Patent as set forth in Exhibit B. Except as expressly admitted, Guardant denies the allegations of this paragraph.

71. Guardant denies the allegations of this paragraph.

72. Guardant denies the allegations of this paragraph.

73. Guardant denies the allegations of this paragraph.

74. Guardant denies the allegations of this paragraph.

75. Guardant denies the allegations of this paragraph.

COUNT III

([Alleged] Infringement of U.S. Patent No. 10,752,951)

76. Guardant incorporates its responses to Paragraphs 1-75 above, as if fully set forth herein.

77. Guardant admits that this paragraph recites claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

78. Guardant denies the allegations of this paragraph.

79. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

80. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

81. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

82. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

83. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

84. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

85. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

86. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

87. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

88. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

89. Guardant admits that this paragraph recites a portion of claim 1 of the '951 Patent as set forth in Exhibit C. Except as expressly admitted, Guardant denies the allegations of this paragraph.

90. Guardant denies the allegations of this paragraph.

91. Guardant denies the allegations of this paragraph.

92. Guardant denies the allegations of this paragraph.

93. Guardant denies the allegations of this paragraph.

94. Guardant denies the allegations of this paragraph.

COUNT IV

([Alleged] Infringement of U.S. Patent No. 10,760,127)

95. Guardant incorporates its responses to Paragraphs 1-94 above, as if fully set forth herein.

96. Guardant admits that this paragraph recites claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

97. Guardant denies the allegations of this paragraph.

98. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

99. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

100. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

101. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

102. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

103. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

104. Guardant admits that this paragraph recites a portion of claim 1 of the '127 Patent as set forth in Exhibit D. Except as expressly admitted, Guardant denies the allegations of this paragraph.

105. Guardant denies the allegations of this paragraph.

106. Guardant denies the allegations of this paragraph.

107. Guardant denies the allegations of this paragraph.

108. Guardant denies the allegations of this paragraph.

109. Guardant denies the allegations of this paragraph.

JURY DEMAND

110. This paragraph sets forth Plaintiffs' request for a jury trial to which no response is required.

PRAYER FOR RELIEF

These paragraphs set forth the statement of relief requested by Plaintiffs, to which no response is required. To the extent a response is required, Guardant denies that Plaintiffs are entitled to any relief whatsoever, either legal or equitable, from Guardant or this Court. Further, Guardant denies that this is an exceptional case such that an award of attorneys' fees to Plaintiffs or an award of enhanced damages.

GENERAL DENIAL AND NON-WAIVER

Each and every allegation in the Complaint not specifically admitted is denied, and the failure to deny a specific allegation, or assert a specific defense, shall not be deemed to be an admission of an allegation or a waiver of a defense.

AFFIRMATIVE DEFENSES

Without assuming any burden of proof that it would not otherwise bear, Guardant asserts the following separate and additional defenses, all of which are pled in the alternative, and none of which constitutes an admission that Guardant is in any way liable to Plaintiffs, that Plaintiffs have been or will be injured or damaged in any way, or that Plaintiffs are entitled to any relief whatsoever. In addition to the affirmative defenses described below, subject to its responses above, Guardant specifically reserves all rights to allege additional affirmative defenses that become known through the course of discovery.

**FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)**

Plaintiffs' claims are barred wholly or in part because Plaintiffs have failed to state any claim upon which relief can be granted with respect to Guardant with sufficient specificity and/or factual support to put Guardant on notice as to the claim being made and therefore failing to state a claim on which relief can be granted.

Plaintiffs fail to state a claim for willful infringement for failing to identify any pre-suit factual basis that Guardant had actual knowledge of or was willfully blind to any of the Asserted Patents or Guardant's alleged infringement, and for failing to plausibly allege facts sufficient to show that this is an egregious case of culpable behavior warranting enhanced damages.

**SECOND AFFIRMATIVE DEFENSE
(No Infringement)**

Guardant has not, does not, and will not directly or indirectly infringe any valid and enforceable claim of the '631 patent, the '699 patent, the '951 patent, and the '127 patent in any manner under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g) literally or under the doctrine of equivalents, willfully or otherwise. Guardant has not performed any act and is not proposing to perform any act in violation of any rights validly belonging to Plaintiffs.

Certain claims of the '631 patent, the '699 patent, the '951 patent, and the '127 patent recite methods and require, for direct infringement, Guardant to perform every recited step of every asserted claim according to the limitations described in each asserted claim. Neither Guardant itself, nor any Guardant employee, performs all of the required steps of the asserted method claims while using any accused product.

**THIRD AFFIRMATIVE DEFENSE
(Invalidity)**

One or more claims of the '631 patent, the '699 patent, the '951 patent, and the '127 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code including, but not limited to, Sections 101, 102, 103 and/or 112.

**FOURTH AFFIRMATIVE DEFENSE
(Inventorship/Derivation)**

One or more claims of the '631 patent, the '699 patent, the '951 patent, and the '127 patent are invalid for failure to name the correct inventors pursuant to 35 U.S.C. § 116 and/or the claims were derived from the inventions of others.

**FIFTH AFFIRMATIVE DEFENSE
(Standing)**

One or both of the Plaintiffs lack standing to assert one or more of the Asserted Patents.

**SIXTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)**

One or more claims of the '631 patent, the '699 patent, the '951 patent, and the '127 patent are and were limited by amendment, the prior art and/or by the statements made during prosecution before the PTO such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the '631 patent, the '699 patent, the '951 patent, and the '127 patent are of sufficient scope to cover the products accused of infringement in this case either literally or under the doctrine of equivalents.

**SEVENTH AFFIRMATIVE DEFENSE
(Waiver, Estoppel)**

Plaintiffs' Complaint is barred by the doctrines of waiver and/or estoppel due to Plaintiffs' actions before, during, and after prosecution of the Asserted Patents, and Plaintiffs' conduct before filing this action and in filing of this action.

**EIGHTH AFFIRMATIVE DEFENSE
(Unclean Hands)**

Plaintiffs' Complaint is barred by the doctrine of unclean hands as a result of the acts, conduct, and omissions of Plaintiffs or others that are attributable to Plaintiffs before, during, and after prosecution of the Asserted Patent and Plaintiffs' conduct before filing this action and in filing of this action.

**NINTH AFFIRMATIVE DEFENSE
(Notice, Damages and Cost)**

Plaintiffs' claims for damages are statutorily limited under 35 U.S.C. § 286 and 287.

Plaintiffs are barred from recovering costs in connection with this action under 35 U.S.C. § 288.

Plaintiffs' claims for relief are limited by the doctrines of full compensation, exhaustion, first sale and Plaintiffs are not entitled to double recovery.

**TENTH AFFIRMATIVE DEFENSE
(No Right to Injunctive Relief)**

Plaintiffs are not entitled to preliminary or permanent injunctive relief, *inter alia*, because any injury to Plaintiffs is not immediate nor irreparable, and Plaintiffs have an adequate monetary remedy for any claim that they can prove, subject to any applicable defense and/or set-off.

**ELEVENTH AFFIRMATIVE DEFENSE
(No Pre-Suit Damages, Failure to Mark)**

Plaintiffs' claims for pre-suit damages are limited by any noncompliance with the marking and actual notice requirements set forth in 35 U.S.C. § 287(a).

RESERVATION OF AFFIRMATIVE DEFENSES

As Guardant's investigation is ongoing and discovery has not yet been completed, Guardant is without complete information regarding the existence or non-existence of other facts or acts that would constitute a defense to the purported causes of action in Plaintiffs' Complaint. Accordingly, Guardant reserves the right to assert any other defenses that discovery may reveal.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Guardant demands a trial by jury of all issues presented by Plaintiffs' Complaint that are so triable.

PRAYER FOR RELIEF

WHEREFORE, Guardant prays for judgment as follows:

1. A judgment dismissing Plaintiff's Complaint against Guardant with prejudice;
2. A declaration that Guardant has not infringed, contributed to the infringement of, or induced others to infringe, either directly or indirectly, any valid claims of '631 patent, the '699 patent, the '951 patent, and the '127 patent;
3. A judgment that the '631 patent, the '699 patent, the '951 patent, and the '127 patent be found invalid;
4. A judgment that the Court find this case exceptional under 35 U.S.C. § 285 and order an award to Guardant of its fees and expenses of litigation; and
5. Such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Guardant respectfully demands a jury trial of all issues triable to a jury in this action.

Dated: October 1, 2021

Respectfully submitted,

OF COUNSEL:

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